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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
04/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,449	PAI ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *5 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 6-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I (claims 1-19) and election of species in the in the following table,

No.	Species	Election
1.	1-5, 9, 10, 20 & 22 Water-soluble drug	Insulin
2.	1, 6, 7, 9, 10 & 20 Counter-ion substance	Sodium salt of C8-C18 fatty acid
3.	1, 11, 12 & 20 Lipid	monoglyceride
4.	1, 13 & 20 Polymer	Methacrylic acid copolymer
5.	17 & 18 Cryoprotecting agent	mannitol
6.	1, 14, & 20 Emulsifier	Polyoxyethylene polyoxypropylene copolymer
7.	22 pH adjusting agent	Citric acid

reply filed on 2/27/08 is acknowledged. The traversal is on the ground(s) that the instant invention is provides an orally administrable composition comprising nanoparticles with a particle size of 500 nm or less, comprising 0.1-30% weight of complex water soluble drug and a counter ion substance, 0.5-80 wt% of a lipid, 0.5-80 wt% of a polymer and 1-80 wt% of an emulsifier wherein the weight ratio of lipid and polymer is in the range 1:0.05-3 and such subject matter is absent in the cited reference of Sakuma. This is not found persuasive because, the orally administrable composition containing the nanoparticles is not a single composition wherein the total %wt of individual components add up to 100%. The claim as recited provides broad range of %wt for each individual components and the cited reference of Sakuma discloses a nanoparticle composition for oral administration comprising nanoparticle containing hydrophilic drugs such as salmon calcitonin (sCT)(page 27, column 1, paragraph 2) or insulin (page 24, column 2, bridging paragraph) wherein the size of the nanoparticles ranged from 400

to 1250 nm and % of incorporation of sCT ranged from 9-100 depending on the type of nanoparticle (Table 2, page 27) and the cited reference also discloses that presence of surfactants enhanced the absorption of poor absorptive drugs (page 28, column 2 paragraph 2). Although, the cited reference of Sakuma does not recite the widely varying %wt of different ingredients of the instant invention as alleged by applicants, the cited reference teaches the general concept of the nanoparticle drug composition which is the technical feature of the instant invention. As stated by the applicants, "[A]dditionally, Applicants take this opportunity to point out that the technical feature of the present invention is containing nanoparticles with the particle size of 500 nm or less and adding specific wt% ranges of complex of water-soluble drug and a counter-ion substance, lipid, polymer and emulsifier, and not necessarily in the selection of the specific kinds of water-soluble drug, counter-ion substance, lipid, polymer and emulsifier. Thus there should be no need to restrict the above materials to their specific types. Further, a cryoprotecting agent and pH adjusting agent are additional components, and therefore, there should also be no need to restrict these components to their specific types". Thus according to applicants, the instant invention is drawn nanoparticles 500 nm or less and adding specific %wt ranges of complex of water soluble drug and a counter ion, lipid, polymer and emulsifier and not any particular species of variety of genera of ingredients. As stated above the %wt of different ingredients do not add up to 100% to impart specificity to the claim as recited. Further, MPEP 1801states that "Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no

technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept". Here, as stated in the rejections below, the claims lack both novelty and inventive step.

The requirement is still deemed proper and is therefore made FINAL.

Applicants request to rejoin the method claims will be considered once the allowable subject matter in the elected invention is identified. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1-23 are pending.

Claims 5 have been withdrawn from further consideration as being drawn to non-elected species. Art was found on the elected species of insulin and has been applied in the rejections below. Hence claim 5 which is drawn to drug which is one charged in water has been withdrawn from further consideration.

Claims 20-23 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1-19 are examined on the merit.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. In the instant case foreign priority to foreign application 'Republic of Korea 10-2003-0096641 dated 12/24/2003 will not be granted for the following reason.

Perfecting a claim to priority under 35 U.S.C. 119(a)-(d) within the time period set in 37 CFR 1.55(a)(1) or filing a grantable petition under 37 CFR 1.55(c). See MPEP § 201.13. The foreign priority filing date must antedate the reference and be perfected. The filing date of the priority document is not perfected unless applicant has filed a certified priority document in the application (and an English language translation, if the document is not in English) (see 37 CFR 1.55(a)(3)) and the examiner has established that the priority document satisfies the enablement and description requirements of 35 U.S.C. 112, first paragraph. (see MPEP 706.02).

Claim Objections

Claims 1, 9-11 and 17-19, objected to because of the following informalities: The claims uses symbol "~" in reciting numerical ranges. The symbol "~" is generally associated with the term "nearly" and not "to" as intended in the instant claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites a limitation 'wherein 80% or more of the water soluble drug is retained in the presence of pancreatin'. It is unclear from the claimed invention how the pancreatin is associated with the composition claimed. Pancreatin is only found in the pancreas. Thus, the claim implies administration to the individual. However, the claims are drawn to a composition and do not require an administration step. Thus, the claim is indefinite.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1-3, 6, 9-11, 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant invention applicants claim a orally administrable composition containing nanoparticle size of 500 nm or less comprising 0.1-30% weight% complex of a water soluble drug and a counter-ion substance 0.5~80 weight% of a lipid, 0.5~80 weight% of a polymer, and 1~80 weight% of an emulsifier, wherein the weight ratio of said lipid and said polymer is in the range of 1:0.05-3.

The claim 1 as recited encompasses any and all water soluble drugs without disclosing any structural or functional attributes of the drugs that constitute a 'water soluble drug'. There are many classes of molecules that fit the generic definition of water soluble molecules, such as peptides, nucleic acids, amino acids, nucleotides, sugars, etc., in which some species of these classes are water soluble and some or not depending on the substitutions or derivatization of either the monomers or the polymers. Thus the genus of water soluble molecules encompasses a very large genera of different classes and subclasses of compounds of known and unknown compounds with a vast array of built in structural and functional complexity. Mere recitation of "a water soluble drug" does not provide written description to the claims as recited. The specification only discloses, insulin and ceftriaxone as drugs in specific examples as water soluble drugs. The claim as recited and the specification as disclosed do not provide a proper definition for the phrase "water soluble drug" and supplement the definition with representative

examples to support the scope of the claim as recited. In addition to this claim as recited claims a "complex of a water soluble drug and a counter ion substance". The nature of the association between water soluble drug and the counter ion substance is not apparent from the claim as recited.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient" MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated: "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure,

formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of

California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

The claim 1 further recites "counter-ion substance". Again the claim as recited and specification does not adequately define the chemical formula or structure associated with the

counter ion substance. The counter ion can be as simple as a alkali atom such as "Na" or "Li" to complex chemical moieties such as lipids carrying + or -ve charge associated with them. The specification provides the following generic definition "A negatively charged substance which can be ionically bonded to a positively charged drug may be preferably selected from the group consisting of sodium salt of C8~18 fatty acid such as sodium oleate, sodium lauryl sulfate, sodium caproate, sodium laurate, etc., sodium salt of bile acid, sodium alginate, and sodium carboxymethylcellulose. A positively charged substance which can be ionically bonded with a negatively charged drug may be preferably selected from a quaternary ammonium compound such as carnitine salt, benzalkonium chloride, cetrimide, etc" (page 12, lines 1-7). The election of species in the instant case as "C8-18" fatty acid genus encompasses innumerable number compounds. The specific examples on pages 19-27 discloses a few charged molecules such as sodium docusate, sodium lauryl sulfate and benzylalkonium chloride, etc., in the composition. The instant disclosure does not adequately support the claims as recited commensurate with the scope of the claims.

Claim 1 also recites other components such as "lipids", "polymer" and "emulsifier". The genus of lipids encompasses multitude of compound that further belongs to several classes of compounds. The term "polymer" and "emulsifier" encompasses any and all known and unknown classes and genera of compounds. The instant specification with only a few representative examples of each of these very broad classes of compounds does not adequately support the vast breadth of the claims as recited.

Therefore, the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 7, 11-15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 771 566 A1 of Fernandez.

In the instant invention applicants claim a orally administrable composition containing nanoparticle size of 500 nm or less comprising 0.1-30% weight% complex of a water soluble drug and a counter-ion substance 0.5~80 weight% of a lipid, 0.5~80 weight% of a polymer, and 1~80 weight% of an emulsifier, wherein the weight ratio of said lipid and said polymer is in the range of 1:0.05-3.

Fernandez teaches a colloidal system comprising nanoparticles, nano capsules and nano emulsions for oral administrations of medicaments (Abstract). The reference discloses negatively charged phospholipid (lecithin), positively charged polysaccharide chitosan, polyoxyethylenenated oils (Migliol), polyepsiloncaprolactone as polymer and drugs such as cyclosporin A, indomethicin, metipropanol and thiopental are as active drugs are used in the nanocoposition (page 3, lines 10-28, and example 1 on page 5). The reference also teaches the

invention can be used to incorporate one or more active ingredients of a hydrophilic or lipophilic character (page 3, lines 21-22). The particle size disclosed in tables 1, 2 and 4 are <500 nm. The %weight of lecithin (a negatively charged molecule) is 1% and % weight of chitosan (a positively charged molecule) is 1% (Example 1) and the % weight of complex of an active molecule associated with the charged molecules is at least 1% (is within the range of 0.1-30% of instant invention), the weight % of lipid (lecithin) is 1% (is within the range of 0.5-80% of instant invention), the weight % of polymer (polyepsiloncaprolactone) is 1% (is within the range of 0.5-80% of instant invention), the weight % of emulsifier (Migliol) is 1.5% (in examples 2 and 3 is within the range of 1-80% of instant invention) and the weight ratio of lipid and polymer in the cited reference is 1 (is within the range of 1:0.05-3). This meets the limitations of claims 1, 11 and 19. Since the drug is encapsulated in the nano particle or nano capsule, it is inherent that 70% or more is entrapped in the nano particles. Hence meets the limitation of claim 2. The lecithin is phospholipid of glycerol origin and a fatty acid (C8-C18) and hence meets the limitations of instant claims 6, 7, 12 and 14. The cited reference of Fernandez also discloses chitosan (Example 1) and hence meets the limitation of claim 13. The cited reference of Fernandez also discloses acetone (25 mL) as a solubilizing agent (page 5, line 38) and hence meets the limitation of instant claim 15. The cited reference of Fernandez also discloses glucose as cryoprotective agent (page 3, lines 17-and 18) and hence meets the limitation of claim 18. Thus the cited reference of Fernandez anticipates the instant claims 1, 2, 6, 7, 12-14 and 17-19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4 and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2004/043513 A2 of Shefer.

In the instant invention applicants claim a orally administrable composition containing nanoparticle size of 500 nm or less comprising 0.1-30% weight% complex of a water soluble drug and a counter-ion substance 0.5~80 weight% of a lipid, 0.5~80 weight% of a polymer, and 1~80 weight% of an emulsifier, wherein the weight ratio of said lipid and said polymer is in the range of 1:0.05-3.

Claim 33 of the cited reference of Shefer discloses the drug insulin as the active ingredient which is a water soluble drug and the drug is encapsulated in a hydrophobic nanosphere as recited in the claim 85 of the cited reference. The claim 25 of the cited reference

discloses a cationic surface active agents consisting of calcium sulfate, sodium lauryl sulfate, etc., that are salts and salts of detergents. Claim 8 of the Shefer reference discloses the elected species of lipid, i.e., monoglyceride. Claim 16 of the Shefer reference discloses polymers such as methacrylate and methacrylic acid. Claim 23 of Shefer discloses ethoxylated/propoxylated block polymers and hence reads on the elected species of emulsifier polyoxyethylene polyoxypropylene copolymer. Claim 82 of the cited reference discloses the size of the nanosphere as 2-30 microns and hence meets the limitation of the nanoparticle range of the instant application. Hence this meets the limitations of instant claims 1, 2, 4, 6, 7, 12, 13 and 15. The cited reference of Shefer discloses benzylalkonium chloride (claim 24) as surface active material and hence meets the limitation of instant claim 8. Claim 42 of the Shefer discloses that the composition comprises of 0 to 30% by weight of surface active agents and 1 to 50% by weight of active ingredients. This meets the limitations of instant 9 and 10 since the disclosed %wt of active ingredients and surface active agents encompass the recited range in the instant claims. Claim 8 of the Shefer reference discloses the elected species monoglyceride and hence reads on instant claim 12. Claim 9 of the Shefer reference discloses the fatty acuid derivatives selected from alcohol and hence reads on instant claim 16. Claim 16 of the Shefer reference also discloses polyethylene oxide (also known as polyethylene glycol) hence reads on instant claim and hence reads on instant claim 16. Claim 23 of Shefer discloses ethoxylated/propoxylated block polymers and hence reads on the elected species of emulsifier polyoxyethylene polyoxypropylene copolymer. Claim 15 of Shefer discloses the elected species of mannitol as water sensitive and hence reads on instant claims 17 and 18.

The reference of Shefer does not disclose range of percentages of recited in claims 1, 11, 15 and 17.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of taught by Shefer to arrive at the instant invention. Because, according to MPEP Section 2144.05, Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The skilled artisan would have been motivated to do because, "[T]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" (MPEP 2144.05). There would have been a reasonable expectation of success, given the fact that Shefer had used the method to successfully incorporate insulin drug in to nanosphere.

Thus, the invention as a whole would have been prima facie obvious to one skilled in the art the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654